Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Resprin Suppositories 150mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Acetylsalicylic acid (Aspirin) 150 mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Suppository
Uniform white suppository.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an analgesic, anti-pyretic and anti-inflammatory agent in the management of mild to moderate fever or pain, such as occurs with headache, toothache, rheumatism, etc.

4.2 Posology and method of administration

For rectal use only.

Dosage

Over 16 years, adults and the elderly:
3-4 suppositories every 4 hours. Not more than 24 suppositories to be used in any 24 hours.

Do not give to children and adolescents aged under16 years, except on medical advice, where the benefit outweighs the risk.

4.3 Contraindications

Known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Prolonged use without medical supervision could be harmful. There is a possible association between Aspirin and Reye’s Syndrome when given to children. Reye’s Syndrome is a very rare disease, which affects the brain and liver, and can be fatal.

For this reason, Aspirin should not be given to children and adolescents aged under 16 years unless specifically indicated. Particular caution is necessary in the presence of viral infections.

4.5 Interaction with other medicinal products and other forms of interaction

If any other medications are being taken or the patient is under the care of a doctor, the possibility of interaction or adverse reaction should be borne in mind. Aspirin may enhance the effects of anticoagulants and inhibit the action of uricosurics. In large doses aspirin may also decrease insulin requirements.

4.6 Pregnancy and lactation

There is clinical and epidemiological evidence of the safety of aspirin in pregnancy but it is best avoided at term as it may prolong labour and contribute to maternal and neonatal bleeding. Breastfeeding is contra-indicated at high doses of aspirin because of the theoretical risk of affecting clotting mechanisms.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Aspirin may precipitate bronchospasm and it can induce attacks of asthma in susceptible individuals.

4.9 Overdose

Resprin overdosage should be treated with evacuation of the bowel, followed by N-acetylcysteine i.v. or l-methionine orally in order to prevent liver damage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aspirin has anti-pyretic, analgesic and anti-inflammatory properties.

5.2 Pharmacokinetic properties

None.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adeps Solidus

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Suppositories are presented in strips of five peel-apart, plastiliaminate moulds. Two strips (ten suppositories) are packed into a cardboard carton. The plastiliaminate consists of a contact layer of polyethylene, an outer layer of polyvinylchloride and polyurethane adhesive layer.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Ricesteele Manufacturing Ltd.
Cookstown Industrial Estate
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 95/6/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 February 1982

Date of last renewal: 17 February 2002

10 DATE OF REVISION OF THE TEXT

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